

Endoscopic Sphincterotomy for Stones By Experts Is Safe, Even in Younger Patients With Normal Ducts

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Objective

To provide current information on the risks of endoscopic sphincterotomy for stone.

Summary Background Data

In recent years (since the popularity of laparoscopic cholecystectomy), endoscopic sphincterotomy has been used increasingly for the management of bile duct stones in relatively young and healthy patients. The validity of this trend has been questioned using data on short-term complications derived from earlier decades that involved more elderly and high-risk patients.

Methods

Seven academic centers collected data prospectively using a common database. Complications within 30 days of the procedures were documented by standard criteria.

Results

Of 1921 patients, 112 (5.8%) developed complications; two thirds of these events were graded as mild (<3 days in hospital). There was no evidence of increased risk in younger patients or in those with smaller bile ducts. There was only one severe complication and there were no fatalities in 238 patients age <60, with bile duct diameters of <9 mm.

Conclusion

Sphincterotomy for stones can be performed very safely by experienced endoscopists.

Endoscopic sphincterotomy was introduced >20 years ago. It rapidly became popular for the treatment of bile duct stones, especially after cholecystectomy, because it was clearly safer, easier, and less expensive than orthodox surgery.¹ Subsequent results have legitimized its use as well in some patients with the gallbladder *in situ* (e.g., those with acute gallstone-related cholangitis and pancreatitis).² Since laparoscopic cholecystectomy was introduced, many healthy patients have undergone endoscopic sphincterotomy, simply because few surgeons currently attempt to explore the duct laparoscopically.³⁻⁵ This has caused concern and raises legitimate questions. How safe is endoscopic biliary sphincterotomy in healthy and young patients, especially those with nondilated ducts? Might traditional open surgery be safer?⁶⁻¹⁰

Surgeons addressing this issue usually quote complication rates for endoscopic sphincterotomy of approximately 10%, with an average mortality of 1%.¹¹ These data are derived from a broad spectrum of patients and indications, including high-risk patients with dilated ducts and recurrent stones, and patients with papillary stenosis, in whom the risks of sphincterotomy are known to be greater.^{12,13} To discuss the relative risks of endoscopic and surgical management of duct stones, we need data that focus on the risks of endoscopic sphincterotomy for stones, in younger patients, with ducts that are not dilated. This study provides data from seven collaborating centers.

PATIENTS AND METHODS

Seven academic centers in the United States agreed to share data collected prospectively concerning all endoscopic sphincterotomy procedures performed for bile duct stones for varying periods between 1990 and 1994. Data elements included age, duct size (measured below the cystic duct junction and corrected for magnification), and short-term complications. Complications were assessed during the 30-day period after endoscopic intervention and stratified using criteria determined by a consensus conference (Table 1).¹¹

RESULTS

Data were received on a total of 1921 sphincterotomies. The overall complication rate was 5.8% (Table 2), with little variation between the centers. There were only 12 (0.6%) severe complications and 4 (0.2%) fatalities. All four deaths were in elderly patients with severe comorbidities. Analysis of the subsets of data showed no greater risk with smaller ducts; indeed, there was a trend toward

Table 1. DEFINITIONS OF COMPLICATION SEVERITY¹¹

Degree of Severity	Definition
Mild	Requiring unplanned hospital admission or prolongation of a planned admission for up to 3 days
Moderate	4–10 days hospitalization, including further endoscopic or radiologic intervention if necessary
Severe	>10 days hospitalization or the need for surgical intervention or intensive care
Fatal	Death attributable to the procedure within 30 days, or longer with continuous hospitalization

increased safety with younger patients and smaller ducts. Of particular pertinence was the low complication rate in the 238 patients who were <60 years old and had bile duct diameters <9 mm; in this group, there was only one severe complication and no mortality (see Table 2). Risks were not significantly different in patients with normal-sized ducts (<7 mm). Even more impressive were the data from 104 patients (a subset of the 238) who underwent their procedures electively as outpatients: there were only 3 complications, all mild.

DISCUSSION

Endoscopic sphincterotomy is accepted as the primary treatment for bile duct stones in elderly and high-risk patients. However, concern has been raised by its widespread use for elective stone extraction in younger and fitter patients, stimulated by the rapid acceptance of laparoscopic cholecystectomy, without duct exploration.^{7,14} The relative risks of open surgery, laparoscopy, and endoscopy in this context are unknown.

Table 2. COMPLICATION RATES FOR SPHINCTEROTOMY*

	All Cases	Duct ≤9 mm	Age <60 yr, Duct ≤9 mm
Total	1921	637	238
Complications	112 (5.8)	33 (5.2)	10 (4.2)
Mild	70 (3.6)	28 (4.4)	7 (2.9)
Moderate	26 (1.4)	8 (1.3)	2 (0.8)
Severe	12 (0.6)	2 (0.5)	1 (0.4)
Fatal	4 (0.2)	0	0

* Values are number (%). None of the differences between groups reached statistical significance.

Our data confirm that experts can perform endoscopic sphincterotomy for stones with remarkable safety. Overall, 112 (5.8%) of 1921 patients developed complications, but only 42 (2.2%) needed hospital care for >3 days. The study included all patients undergoing endoscopic stone management in these centers, including some with severe comorbidity. Results from younger and fitter patients were even more reassuring. There were only 3 complications (all graded mild) in a subgroup of 104 elective outpatient procedures. Freeman et al.¹⁵ recently published similarly low complication rates from another prospective multicenter study.¹⁵ Among 487 patients who underwent sphincterotomy for stones within 30 days of laparoscopic cholecystectomy, complications occurred in only 4.9%, and none was severe. These two studies provide the benchmark figures against which other endoscopic and surgical series may be measured.

What of the suggestion that smaller ducts are more dangerous?^{12,13} This appears to apply only to patients with suspected sphincter of Oddi dysfunction. It was not present in our study, nor in the patients with stones reported by Freeman et al.¹⁵ A British study actually showed the reverse.¹⁶

This study can be criticized on two main counts. First, the reporting centers were all highly experienced, although trainees were involved in most of the procedures. Attempting to obtain a broader view, Davis et al.¹⁷ recruited 45 community gastroenterologists and compared their endoscopic sphincterotomy results with those from expert centers, in the context of laparoscopic cholecystectomy. There was a trend toward better results in more experienced hands (higher success rates and fewer complications), but the differences did not reach statistical significance. In Freeman et al.'s study,¹⁵ there was a slightly lower complication rate (8.4% vs. 11.1%) for all indications among endoscopists doing >1 sphincterotomy per week. The contributors to all of these studies were self-selected and may not be representative of the entire endoscopic community.

Second, we have not presented data on possible long-term complications of sphincterotomy. This is a legitimate concern, especially in young patients.^{18,19} Several medium- to long-term follow-up studies have shown that up to 24% of patients may develop further biliary problems after endoscopic sphincterotomy.^{20–22} However, these studies mainly involved earlier cohorts of elderly and high-risk patients suffering from recurrent or retained stones in dilated ducts (some with the gallbladder *in situ*). More studies are required to address this issue specifically in younger patients with “normal” ducts and with very long-term follow-up.

Sphincterotomy is clearly appropriate in patients with dilated ducts and recurrent stones who may require biliary drainage. However, concerns about complications should

spur efforts to remove bile duct stones by other means in patients with otherwise normal ducts and sphincters.¹⁴ These efforts must include further development of techniques and training for laparoscopic duct exploration^{8,23} and endoscopic extraction of stones without sphincterotomy,^{24,25} perhaps revisiting the use of oral dissolution agents in patients with small stones likely to be rich in cholesterol. These unanswered questions dictate future research projects. Our results show that endoscopic sphincterotomy for stones can be performed very safely. Claims that open surgical or laparoscopic treatment may be safer should be supported by data.

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